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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,844	KRISHNAN, SUBRAMANIAM C.	
	Examiner	Art Unit	
	DEBORAH MALAMUD	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,21,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,21,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Examiner acknowledges the response received 13 February 2009. Claims 1-17, 19-20 and 22-35 are cancelled; claims 18, 21 and 36-37 are pending.

Response to Arguments

2. Applicant's arguments filed 13 February 2009 have been fully considered but they are not persuasive. The Applicant argues (page 6, "Remarks") "Svenson discloses using the distal bipolar electrodes to map areas of ventricular tachycardia [*sic*] within the heart (Col. 5, lines 39-45), not the spaced apart unipolar electrode. In addition, the specification on page 16, lines 23-34 recites the benefits of the use of unipolar signals to locate the fossa ovalis. There is no teaching or suggestion that the Svenson bipolar electrodes located at the distal end of a single catheter have the capability to serve as unipolar electrodes for the generation of unipolar electrograms. Nor is there any teaching or motivation that the Svenson unipolar electrode and the distal tip bipolar electrodes can form a bipolar electrode pair as claimed." In response to applicant's argument that Svenson does not disclose the claimed elements, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Svenson's electrodes are capable of bipolar or unipolar use, and nothing in their structure prohibits them from doing so.

3. The Applicant further argues (page 7, "Remarks") "Svenson fails to disclose a location signal generator for providing a location signal, or impulse, to at least one of the electrodes on the catheter in order to locate the fossa ovalis by measuring, for example, impedance or the pacing threshold of the interatrial septum. In fact, there is no mention at all of a location signal generator in Svenson. In addition, Svenson is completely silent to the use of impedance or pacing threshold measurements in locating the fossa ovalis." The Examiner agrees that Svenson fails to teach this feature, but notes that Eigler indeed discloses it, as previously cited in the prior Office Action. Eigler discloses (col. 3, lines 54-57) placement of the lead and sensor "with the aid of visualization techniques including standard fluoroscopy, cardiac ultrasound, or other appropriate visualization techniques used alone or in combination. It is noted that the claim language of 36 is vague as to this element, requiring only that "a user may identify the fossa ovalis of patient on the basis of at least one of the following parameters." The system of Eigler further (col. 7, lines 65-67; col. 1-8) includes "one or more additional sensors (75) configured to monitor pressure at a location outside the left atrium, or a different physical parameter inside the left atrium or elsewhere. For each sensor, a sensor lead (77 and 80) conveys signals from the sensor to a monitoring unit (82) disposed inside the housing of the unit. It should also be noted that the sensor lead connecting the pressure transducer to the monitoring apparatus might also be combined with or run parallel to another lead such as an electrical EKG sensor lead or a cardiac pacing lead, either of which might be placed in or near the left atrium." Eigler's system is used to

visualize and locate a section of the heart for puncture of the interatrial septum. Therefore it is capable of identifying the fossa ovalis by the claimed parameters.

4. The rejection of the claims is therefore maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 18, 21 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008) in view of Eigler et al (U.S. 6,328,699) (both cited in previous actions). Regarding claims 18, 21 and 36, Svenson discloses (col. 2, lines 30-36) "a mapping catheter which includes a polymer member, bipolar sensing electrodes placed on a distal end of said polymer member, a spaced unipolar electrode at a spaced distance from said bipolar electrodes, and a lumen within said polymer member for the passage of a laser catheter or other instrument." Svenson further discloses, (col. 3, lines 13-17) "a laser delivery catheter can be passed through the center hollow lumen of the mapping catheter and the myocardium irradiated for a predetermined period of time to ablate the site." The examiner considers this to be a hollow lumen, a first electrode positioned on a distal end of the catheter, and a second electrode spaced proximally from the first electrode and positioned on the catheter. Svenson further discloses (col. 3, lines 53-64; Figure 1) "mapping catheter (10)

including the catheter tip (12), the stainless steel support tube (14), the hand piece (16), and the Y-connector (18). The hand piece joins the Y-connector and the stainless steel support tube together and includes the electrical junction (20) of the wires (21a-21c) with electrical connectors (22a-22c), which in this example are insulated alligator clips. A polymer tube-like sheath (24) connects between the catheter tip (12) and the hand piece, and houses a plurality of wires (21a-21c) between the polymer sheath and the underlying stainless steel support tube." The examiner considers this to be a hollow sheath having a distal end. It is to be noted that the functional language and introductory statement of intended use of claims 21 and 36, have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Svenson utilizes a mapping catheter as claimed by the applicant, Svenson is therefore capable of being inserted into a sheath (such as polymer sheath 24), having a needle urged through, and being used as a dilator for performing a transseptal puncture and locating the fossa ovalis, on the basis of the claimed parameters. In addition nothing prevents the catheter of Svenson from being performing these functions. Therefore, they are capable of locating and penetrating the fossa ovalis and being used with a sheath and a needle.

7. Svenson further discloses, (col. 2, lines 56-62) "The current catheter provides a tool for more accurately mapping the electric potential of very small areas of the inner chambers of the heart. In addition, the catheter provides a way to simultaneously obtain the QRS and EKG signals, thus providing a method to more rapidly and accurately identify the focus or foci of the tachycardia." The examiner considers this system

therefore inherently to include a recording device for recording electrograms, the recording device in electrical communication with the electrodes of the catheter. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a recording device for recording electrograms in order to display the data gathered by the electrodes for future diagnosis.

8. Svenson discloses the claimed invention except for a transseptal needle and sensors of electrophysical activity of an interatrial septum. Eigler however discloses (col. 3, lines 30-65; col. 4, lines 1-22; Figure 1) a system for accessing the left atrium "from the right atrium through the atrial septum separating the right and left atria. The flexible lead (10) and pressure transducer (15) will be anchored to the atrial septum." A "Brockenbrough catheter and needle are used to pierce the atrial septum for access to the left atrium." Figure 1 depicts the system, which includes "a Brockenbrough catheter (20) inside a peel-away sheath (22), with a flexible guidewire residing within the Brockenbrough catheter." With the access assembly (18) in place within the right atrium (30), "the Brockenbrough catheter is used to pierce the atrial septum (41) by extending the Brockenbrough needle (not shown) through the atrial septum into the left atrium (36). In the figures, the atrial septum has been pierced by the needle, the catheter advanced over the needle, and the needle withdrawn from the catheter leaving the catheter in place inside the left atrium." The system (col. 7, lines 65-67; col. 1-8) includes "one or more additional sensors (75) configured to monitor pressure at a location outside the left atrium, or a different physical parameter inside the left atrium or elsewhere. For each sensor, a sensor lead (77 and 80) conveys signals from the

sensor to a monitoring unit (82) disposed inside the housing of the unit. It should also be noted that the sensor lead connecting the pressure transducer to the monitoring apparatus might also be combined with or run parallel to another lead such as an electrical EKG sensor lead or a cardiac pacing lead, either of which might be placed in or near the left atrium."

9. Eigler and Svenson both disclose implantable methods and apparatus for detecting signals in the heart in order to diagnose and treat a patient. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Svenson's mapping electrodes with Eigler's transseptal needle and puncture system in order to provide a minimally-invasive technique for gathering interatrial septum data for more accurate patient diagnosis.

10. Further regarding claim 36, Eigler discloses (col. 3, lines 54-57) placement of the lead and sensor "with the aid of visualization techniques including standard fluoroscopy, cardiac ultrasound, or other appropriate visualization techniques used alone or in combination.

11. Regarding claim 37, Svenson and Eigler disclose the claimed invention except for an interelectrode separation of between about 2 mm and about 4 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an interelectrode separation of this length, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, Svenson and Eigler disclose the claimed invention but does not disclose expressly the tapered end of a catheter. It would have been an

obvious matter of design choice to a person of ordinary skill in the art to modify the catheter tip shape as taught by Eigler, with the tapered end as claimed, because the applicant has not disclosed the tapered end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the catheter tip shape as taught by Eigler and Svenson, because it is used to piece the interatrial septum for atrial placement as required by the claim. Therefore, it would have been an obvious matter of design choice to modify Svenson and Eigler to obtain the invention as specified in the claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766